

Abstract

A device for monitoring subject compliance comprising an instrumented paper diary for subjects to record clinical trial data. The instrumented paper diary creates an objective record of the use of the diary to verify subject entries, allowing researchers and clinicians to systematically track the use of the diary in the field. Subjects record clinical trial data in a paper diary. Electronic instrumentation connected to the paper diary allows use of the diary (e.g. when it was opened and closed) to be unobtrusively tracked, recorded and evaluated against how research protocols dictate the diary to be used. The instrumented paper diary creates an objective electronic record of when the diary was being opened/closed or written upon, allowing researchers to confirm whether the date and time written on diary entries correspond to reported diary use. The handwritten entries in the diary can be checked against the electronic record of when the diary was in use to confirm that the person completed the diary entry when they recorded that they completed it. A variety of different types of instrumentation can be used to collect a variety of data regarding the diary use; including whether it is opened, closed, left open for a long period of time, or being carried with people throughout the day.

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